

## REMARKS

### Amendments

5       Independent claims 1 and 20 have been amended by the insertion of a proviso which excludes from the claims any gas-permeable membrane as defined in the claims of Patent No. 6,376,032. Paragraph 2A of Claim 1 has been amended to reflect the fact that the polymeric matrix and the filler have not been referred to earlier in the claim. Typographical errors in claim 1 have also been corrected. Claim 2 has been amended  
10      by way of simplification. Claim 6 has been amended to remove one of the requirements for the pore size of the microporous film. Paragraph 4 of claim 20 has been amended to change one of the limitations on the pore size; basis for this amendment is on page 6, lines 23-24. New claims 30 and 31 have been added to provide dependent claims limited to microporous films containing a siliceous filler.

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### The Election Requirement

20       In response to the election requirement, Applicants affirm the election to prosecute the species polydimethyl siloxane as the coating polymer, without prejudice to Applicants' right to consideration of claims to additional species upon the allowance of a generic claim. The claims directly readable on this species are claims 11 and 26. Claims 12, 14 and 27 (which have been withdrawn from consideration) exclude this species. The other claims include this species within their scope, but are not limited to this species. Applicants note that, contrary to the statement in the Office Action that  
25      "currently, no claim is generic", claims 1 and 20 (both as examined and as amended by this paper) are generic claims, since they encompass not only the elected species, but also the non-elected species.

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### The Objection to the Specification

Applicants respectfully traverse the objection to the specification. In the application as filed, paragraph 1 of claim 9 provides basis for the statement that substantially 100% of the pores in the microporous film have a pore size of less than

5 0.24 micron.

The Rejection on the ground of Double Patenting

Applicants respectfully traverse the rejection of claims 1-4, 6-8, and 14-16 over

10 U.S. Patent No. 6,376,032 under the judicially created doctrine of double patenting, and the rejection of claims 20-21, 23-25 and 29 under the judicially created doctrine of obviousness-type double patenting, insofar as those rejections are applicable to the amended claims.

15 As noted above, the independent claims of this application (claims 1 and 20) have been amended to exclude the crystalline polymeric coatings which are an essential feature of the claims of U.S. Patent No. 6,376,032. Since there is now no overlap between the claims of this application and the claims of U.S. Patent No. 6,376,032, it is submitted that the rejections on the ground of double patenting should

20 be withdrawn. Furthermore, it is pointed out that, in the elected claims, the coating polymer, polydimethyl siloxane, is an amorphous polymer; this is clearly contrary to the requirement of the claims of U.S. Patent No. 6,376,032 that the coating polymer is a crystalline polymer having a narrow melting point range.

25 The Rejection under 35 U.S.C. 102

Applicants respectfully traverse the rejection of Claims 1, 2, 7, 8, 11, 13 and 15-16 under 35 U.S.C. 102 as anticipated by Antoon (U.S. Patent No. 5,160,768), insofar as that rejection is applicable to the amended claims, for following reasons.

Initially, it is noted that, of the claims rejected under 35 U.S.C. 102, only claim 2 was also rejected under 35 U.S.C. 103, although the discussion of the 35 U.S.C. 102 rejection in the Office Action includes language such as "if the applicant intends... to show nonobviousness". It is also noted that paragraph 3 of the Office Action contains a 5 sentence which appears to be irrelevant to the rejection of the 35 U.S.C. 102, namely "The U.S. Patent 6,376,032 either anticipated or strongly suggested the claimed subject matter".

Claim 1, and claims 2, 7, 8, 11, 13, and 15-16 which are dependent on claim 1, 10 are directed to gas-permeable membranes in which the microporous film has been prepared by passing a continuous sheet comprising a powdered polymer, a filler, and a processing oil through calendar rolls to reduce its thickness; treating the calendered sheet with an organic extraction liquid which removes the processing oil; and removing the extraction liquid by steam or water or both. It is clear that Antoon does not disclose 15 membranes made by such a process. The process used by Antoon to prepare his microporous sheets is disclosed in column 4, lines 48-59. It involves casting a sheet of a mixture of a polymer and a filler, and drawing the sheet to effect orientation of the polymer along its longitudinal and transverse axis. During the process, "the polymer pulls away from the filler material causing voids and pores to form in the film matrix". 20 The degree of permeability that results is stated to be "a function of the amount of filler in the polymer, the amount of draw imposed upon the polymer and the temperature at which the drawing is carried out".

The Examiner has not suggested that the process defined in Claim 1 to prepare 25 the microporous sheet is the same as, or obvious having regard to, the process disclosed in Antoon for preparing his microporous sheet. Rather, the Examiner has asserted

(1) that the gas-permeable membrane disclosed by Antoon is "identical to or only slightly different than" the gas-permeable membrane prepared by the 30 method defined in Claim 1, because both comprise a microporous film and a polymeric coating on the film, and both have an oxygen permeance (i.e. OTR) of

at least 775,000 ml/m<sup>2</sup>.atm.24 hrs (50,000 cc/100 in<sup>2</sup>.atm.24 hrs) and a CO<sub>2</sub>/oxygen permeability ratio (R) of at least 1.5, as required by Applicants' claim 1; and

(2) that, in view of (1), Claim 1 is unpatentable, even though the

5 microporous sheet was made by a different process, having regard to the decisions in *In re Thorpe* and *In re Marosi*.

As noted in paragraph 6 of the accompanying Declaration, it is factually incorrect to assume that Antoon's gas-permeable membrane and Applicants' gas-permeable  
10 membrane are "identical or only slightly different" because both have OTR and R values above the minima stated in Claim 1; and it would likewise be factually incorrect to make that assumption even if both gas-permeable membranes had the same polymeric coating.

15 The processes defined in Claim 1 and in Antoon, and the products of those processes, are discussed in detail in the accompanying Declaration by Raymond Clarke  
As noted at the beginning of paragraph 9 of the Declaration

*The drawing process used by Antoon to prepare his microporous films is clearly different from the extraction process preferably use prepare the microporous films in the present application. Furthermore the different processes produce microporous films which are quite different from each other.*

The remainder of paragraph 9 and paragraphs 10-12 of the Declaration provide a detailed justification for this statement. The following points in particular are noted.

20 1. In Antoon's drawing process, the voids are produced by sudden violent rupture of the polymeric matrix. In the extraction process, the polymeric matrix remains substantially unchanged, and the voids are produced by removal of processing oil from pockets and channels whose shapes depend on the viscosities and surface tensions of the polymer and the processing oil during the melt processing step. The voids remaining after the extraction step are, therefore, quite different from those produced by Antoon's  
25 drawing process.

2. Antoon's drawing process results in microporous sheets which, by comparison with those produced by the extraction process, are less consistent in their pore sizes, have a wider range of pore sizes and have a greater proportion of larger pores. As a result, coated membranes based on Antoon's microporous sheets are inferior to those

5 based on microporous sheets prepared by the extraction process or which have pore size characteristics similar to sheets prepared by the extraction process.

3. Antoon's specific Examples make it clear that his coated products suffer from the disadvantages that result from a wide range pore sizes and the presence of substantial proportions of larger pores. In particular, neither the OTR nor the R ratio of the coated

10 membranes is a function of the coating weight of the polymer.

4. Comparison of Antoon's specific Examples and the specific Examples of the present application using the same coating polymer demonstrates the improved results obtained when using a microporous film prepared by the extraction process, Teslin SP7, and having, in consequence, relatively small proportions of larger pores.

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New Claim 30, which is dependent on claim 1 and which specifies that the filler is a siliceous filler, is yet more clearly distinguished from Antoon, in which, in all the specific films used by Antoon, the filler is calcium carbonate.

20 The Rejection under 35 U.S.C. 103

Applicants respectfully traverse the rejection of claims 2-6, 20-26 and 28 under 35 U.S.C. 103 as obvious over Antoon (U.S. Patent No. 5, 160,768), insofar as that rejection is applicable to the amended claims, for following reasons.

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As noted by the Office Action, Antoon "fails to teach the recited average pore size and densities of the pores". However, the Office Action asserts that, since Antoon teaches a gas permeable membrane having the OTR and R ratio specified in the claims, it would have been obvious to one of ordinary skill in the art to have provided the

30 specified pore size and density. Applicants submit that that assertion is wrong, and that, insofar as Antoon contains any teaching about the pore size characteristics of the

microporous films, Antoon teaches away from the limitations in the rejected claims, in particular the requirements that at least a minimum percentage of the pores should have a size less than a particular value.

5           Column 3, lines 30-34, of Antoon states

*A critical feature for high permeance and high CO<sub>2</sub> :O<sub>2</sub> ratio... is that the substrate film, although often much thicker than the coating, should be at least two times (preferably at least 10 times) as permeable as the coating itself.*

Column 3, lines 60-65, of Antoon states

10           The preferred microporous membrane is a polypropylene film filled with 50 to 65% of CaCO<sub>3</sub> that is uniaxially oriented because this uniaxially oriented film has narrow elongated pores on the surface that are more readily bridged by an intact silicone membrane.

15           The first quoted passages does not refer directly to the pore sizes in the microporous film. But, as noted in paragraph 7 of the accompanying Declaration, since larger pore sizes result in greater permeance, the teaching of this passage is that large pore sizes are better than small pore sizes. This is, of course, the reverse of Applicants' teaching. The second quoted passage points to the desirability of "narrow elongated pores" when using films containing polypropylene as the polymer and CaCO<sub>3</sub> as the filler, but says  
20           nothing about the size of the pores. There is, therefore, nothing in Antoon which would lead one of ordinary skill in the art to expect that it is desirable to use a film having only a limited number of larger pores, still less to use a microporous film fulfilling the very particular requirements of many of the rejected claims.

25           Applicants agree with the Examiner's statement that Antoon "fails to teach the recited average pore size and densities of the pores". Nevertheless, Applicants recognize that if it could be shown that the microporous films referred to in Antoon do in fact have the limitations on pore size set out in a particular claim, then those limitations would not be important to the patentability of the claim. The Examiner has not pointed to  
30           any reason or evidence that any of Antoon's microporous films do meet the limitations on pore size set out in any of the rejected claims. Applicants submit, therefore, that the

patentability of Applicants' claims must be assessed on the basis that none of Antoon's microporous films meet those limitations. However, Applicants have carefully considered whether any of Antoon's microporous films do in fact meet the limitations on pore size in any of the claims.

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The microporous films used by Antoon are prepared by the drawing process described in Antoon. Substantially the same process is described in U.S. Patent No. 4,879,078, which was filed about seven months before Antoon, and in which the inventor (Antoon) and the assignee (Hercules Inc.) are the same as in Antoon. U.S. Patent No. 4,879,078 is of record. As discussed above in connection with the rejection under 35 U.S.C. 102, that drawing process results in microporous sheets which, as compared to microporous sheets produced by the extraction process, are less consistent in their pore sizes, have a wider range of pore sizes and have a greater proportion of larger pores; and the results set out in Antoon's specific Examples confirm that fact.

So far as Applicants are aware, it is no longer possible to obtain microporous films made by Antoon's drawing process. However, as set out in detail in paragraph 13 of the accompanying Declaration, Applicants have been able to obtain a microporous film which is believed to be a microporous film made by Antoon's drawing process which was supplied by Hercules Inc. (Antoon's assignee) to a company called Fresh King Inc. (whose assets were acquired by Apio Inc., now a subsidiary of Landec Corp., the assignees of the present application) for use in the way set out in U.S. Patent No. 4,879,078. That product has been analyzed, and has been shown to be composed of polypropylene having calcium carbonate dispersed therein. That product has also been subjected to mercury porosimetry, and Table C below (which is the same as Table C in paragraph 13 of the accompanying Declaration) sets out the pore size characteristics in relation to the various limitations present in claims 20-23.

Table C

	Claim 20	Fresh King
Average Pore Size (micron)	< 0.24	0.132
% pores < 0.24 micron	> 70%	82 %
% pores < 0.014 micron	< 20%	22%
% pores < 0.15 micron	> 80%	57%
	Claim 21	
% pores < 0.24 micron	> 90%	82 %
	Claim 22	
% pores < 0.24 micron	100%	82%
	Claim 23	
% pores < 0.11 micron	> 70%	40%

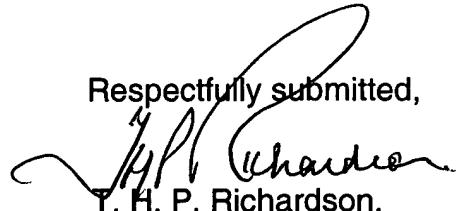
As noted in the accompanying declaration, Table C makes it clear that the microporous  
5 film, although it has an average pore size less than the permitted maximum of 0.24 micron, has many more pores whose size is greater than 0.15 micron than is permitted by the definition in Claim 20. Similarly, it contains too many relatively large pores to meet the requirements of claims 21-23

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## CONCLUSION

It is believed that this application is now in condition for allowance, and such action at an early date is earnestly requested. If, however, there are any outstanding issues that could usefully be discussed by telephone, the Examiner is asked to call the  
15 undersigned.

Respectfully submitted,



T. H. P. Richardson,

Registration No.28,805

Tel No. 650 854 6304

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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Clarke et al

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Group Art Unit: 1772

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Examiner Rhee, Jane J

Title: Gas-permeable Membrane

VERSION OF AMENDED CLAIMS WITH MARKINGS TO SHOW CHANGES  
REQUESTED BY THE ACCOMPANYING REPLY, FILED IN ACCORDANCE WITH 37  
CFR 1.121(c)(1)(ii).

This paper sets out a version of each of the claims rewritten as requested by the accompanying Reply (but not the claims which were unchanged or added by the Reply), marked up to show all the changes relative to the previous version of the claim. In this version,

- (i) a parenthetical expression (which is the same as the parenthetical expression in the clean version of claims set out in the Reply) follows the claim number and indicates the status of the claim as amended, and
- (ii) the changes are shown by square brackets (for deleted matter) and underlining (for added matter).

1. (Amended) A gas-permeable membrane which is useful in the packaging of respiring biological materials and which comprises

- (c) a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film, and
- (b) a polymeric coating on the microporous film,

wherein

- (1) the pores in the microporous film have an average pore size of less than 0.24 micron; and
- (2) the microporous film was prepared by a process comprising the steps of

(A) preparing a uniform mixture comprising [the] a polymeric matrix material in the form of a powder, [the] a finely divided, particulate, substantially water-insoluble filler, and a processing oil;

(B) extruding the mixture as a continuous sheet;

(C) forwarding the continuous sheet, without drawing, to a pair of heated calender rolls;

(D) passing the continuous sheet through the calender rolls to form a sheet of lesser thickness;

(E) passing the sheet from step (D) to a first extraction zone in which [to] the processing oil is substantially removed by extraction with an organic extraction liquid which is a good solvent for the processing oil, a poor solvent for the polymeric matrix material, and more volatile than the processing oil;

[(H)](F) passing the sheet from step (E) to a second extraction zone in which the organic extraction liquid is substantially removed by steam or water or both; and

[(I)](G) passing the sheet from step (F) through a forced air dryer to remove residual water and organic extraction liquid; and

(3) the polymeric coating has a thickness such that the membrane

(iii) has a  $P_{10}$  ratio, over at least one 10 °C range between -5 and 15°C, of at least 1.3;

(iv) has an oxygen permeability (OTR), at all temperatures between 20 and 25 °C, of at least 775,000 ml/m<sup>2</sup>.atm.24 hrs (50,000 cc/100 inch<sup>2</sup>.atm.24 hrs; and

(iii) has a CO<sub>2</sub>/O<sub>2</sub> permeability ratio(R) of at least 1.5; the P<sub>10</sub>, OTR and R values being measured at a pressure of 0.035 kg/cm<sup>2</sup> (0.5 psi);

subject to the proviso that the polymeric coating does not comprise a crystalline polymer having a peak melting temperature  $T_p$  of -5 to 40 °C, an onset of melting temperature  $T_o$  such that  $(T_p - T_o)$  is less than 10 °C, and a heat of fusion of at least 5 J/g.

2. (Amended) A membrane according to claim 1 wherein the [microporous film comprises a] polymeric matrix material is selected from the group consisting of

- (iii) an essentially linear ultrahigh molecular weight polyethylene having an intrinsic viscosity of at least 18 deciliters/g and
- (iv) an essentially linear ultrahigh molecular weight polypropylene having an intrinsic viscosity of at least 6 deciliters/g.

6. (Amended) A membrane according to claim 1 wherein at least 80% of the pores in the microporous film have a pore size less than 0.15 micron [and at least 70% of the pores have a pore size less than 0.11 micron].

20. (Amended) A gas-permeable membrane which is useful in the packaging of respiring biological materials and which comprises

- (c) a microporous polymeric film comprising a network of interconnected pores such that gases can pass through the film, and
- (b) a polymeric coating on the microporous film,

wherein

- (1) the pores in the microporous film have an average pore size of less than 0.24 micron;
- (2) at least 70% of the pores in the microporous film have a pore size of less than 0.24 micron;
- (3) less than 20% of the pores in the microporous film have a pore size less than 0.014 micron;
- (5) [less than 20%] at least 80% of the pores in the microporous film have a pore size [greater than 0.13] less than 0.15 micron; and

(5) the polymeric coating has a thickness such that the membrane

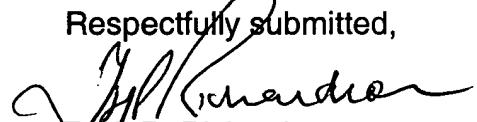
(iii) has a  $P_{10}$  ratio, over at least one  $10^{\circ}\text{C}$  range between -5 and  $15^{\circ}\text{C}$ , of at least 1.3;

(iv) has an oxygen permeability (OTR), at all temperatures between  $20^{\circ}$  and  $25^{\circ}\text{C}$ , of at least  $775,000 \text{ ml/m}^2.\text{atm.24 hrs}$  ( $50,000 \text{ cc/100 inch}^2.\text{atm.24 hrs}$ ; and

(iii) has a  $\text{CO}_2/\text{O}_2$  permeability ratio( $R$ ) of at least 1.5; the  $P_{10}$ , OTR and  $R$  values being measured at a pressure of  $0.035 \text{ kg/cm}^2$  ( $0.5 \text{ psi}$ );

subject to the proviso that the polymeric coating does not comprise a crystalline polymer having a peak melting temperature  $T_p$  of -5 to  $40^{\circ}\text{C}$ , an onset of melting temperature  $T_o$  such that  $(T_o - T_p)$  is less than  $10^{\circ}\text{C}$ , and a heat of fusion of at least 5 J/g.

Respectfully submitted,



T. H. P. Richardson

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Tel No. 650 854 6304